



Standard Procedure

TITLE: Product Identification and Traceability

PROCEDURE: QP-753

Revision 004 – 2/18/18

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1. PURPOSE

- 1.1 To provide for a system and instructions, to assign responsibilities for product identification and traceability.
- 1.2 To provide for a system and instructions, to assign responsibilities for identification of a product inspection status.

2. SCOPE

- 2.1 Applies to materials, components, and other products intended for incorporation into the final products sold by Nanophase Technologies Corporation including final products.
- 2.2 Applies to raw materials, packaging components, and finished products that are subject to inspections and/or testing.

3. RESPONSIBILITY

- 3.1 Materials Department and QA is responsible for assigning product numbers and part numbers to raw materials and finished products.
- 3.2 Process Engineering or R&D is responsible for assigning part numbers to process equipment and related components and experimental products manufactured by NTC.
- 3.3 Quality Department is responsible for assigning batch or lot numbers to raw material. QA is also responsible for assigning batch numbers to cGMP packaged material.
- 3.4 Production Department is responsible for assigning lot or batch numbers to standard products manufactured by NTC. They are also responsible to identify inspection status of product during the manufacturing by the use of pre-established labeling.
- 3.5 QA and Production Departments are responsible to identify inspection status of product during the manufacturing and storage.



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4. ASSOCIATED MATERIALS

- 4.1 Verification of Purchased Products (QP-743)
- 4.2 Batch Labels (QA-134) and Batch Records
- 4.3 Sampling Plan, Inspection and Identification of Incoming Raw Materials (QA-030)
- 4.4 Assignment of Batch/Lot Numbers (QA-133)
- 4.5 Assignment of Batch/Lot Numbers for Experimental Products (QA-137)
- 4.6 Raw Material (RM) & Critical Part (CP) Specification List
- 4.7 Control of Nonconforming Products (QP-831)
- 4.8 Finished Products Inspection and Release for Shipping (QA-151)
- 4.9 In Process Inspection (QP-824)
- 4.10 Final Inspection and Release Process (QP-825)
- 4.11 Quality Control Test Request and Inventory Release Process (QA-350)
- 4.12 ISO 9001-2015 Section 8.5.2

5. PROCEDURE

5.1 Identification

- 5.1.1 Purchased raw materials intended for incorporation into the company's products are assigned and marked with a part number followed by a unique lot number by Quality Department. (QA-030)
- 5.1.2 All Products manufactured by NTC are assigned and labeled with a unique batch or lot number. The manufacturing department is responsible for assigning batch or lot numbers to standard products. QA is responsible for assigning batch numbers to cGMP packaged material. (QA-133)
R&D or Process Engineering assigns experimental product lot or batch numbers. (QA-137)
- 5.1.3 The batch/lot records, inspection records, test records, cleaning records and any other documents created during manufacturing, packaging, inspection, and testing of a product are identified with its batch or lot number.
- 5.1.4 In addition to lot or batch numbers, all raw materials, in process and finished products are always labeled with their chemical or identification name and any other applicable safety information.



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5.2 Traceability

- 5.2.1 Nanophase maintains complete forward and reverse traceability for its manufactured products.

Reverse Traceability

Batches are traceable to raw material used, records related to testing and inspection, production and packaging steps, and equipment used during the manufacturing.

Forward Traceability

All critical raw materials are also traceable to the production batches utilizing them.

- 5.2.2 Purchased products are traceable to their purchase orders and to their original inspection, testing, or lab analysis reports, or other such quality records supplied with the products.
- 5.2.3 During production, traceability is maintained using batch records, inspection records, raw materials (listed in batch record) and other such documents and records established during the manufacture, packaging, inspection, and testing of a product. In these documents, process operators and inspectors record batch numbers of materials used; identify process and inspection equipment and their operators; note process parameters; identify personnel performing final labeling operations; and record other such information necessary to satisfy traceability requirements.

5.3 Traceability Records

- 5.3.1 Traceability records are maintained or coordinated by Quality Department. The record consists of purchase orders for purchased raw materials, packaging components; raw material inspection and testing reports; process data; and product inspection and testing reports. The exact scope of the required traceability record for a given product is documented in manufacturing specifications and Control Plans.
- 5.3.1 Whenever possible and practical, traceability information is recorded directly on the batch records or attached to the batch record.

The following information is recorded to provide traceability for a particular production batch or lot;

- equipment cleaning reports
- raw materials used,
- equipment used,
- testing and inspection records along with instrument used
- process parameters,
- deviation reports
- Out of Specification(OOS) Reports, and
- other traceability information, as required.



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5.3.1 Records are kept by following Control of Quality Records QP-423.

5.4 Inspection Status

5.4.1 General

Following every inspection or testing specified, products are identified indicating “pass” or “fail” inspection. This is to prevent nonconforming product from being used or shipped.

5.4.2 Raw Materials and Packaging Components, and Contact Utilities

All received critical raw material and packaging components are tagged with Quarantine label and not allowed to be used in production. Products that pass the receiving inspection are labeled with green “Released” tag.

Product contact utilities that are filled in bulk storage tanks are controlled by a copy of a completed specification sheet. In this case, control labels are affixed to specification sheet which is kept on the production floor.

(NOTE: There are no designated areas assigned to control the movement of materials, all materials are controlled through the use of control labels)

Product that fails the inspection is labeled with a red “Rejected”. Nonconforming products are handled according to SOP Control of Nonconforming Products QP-831.

5.4.3 In-process Product

Products during manufacturing operations and processes are accompanied by a batch record. Personnel performing process related in-process inspections (e.g., recording process parameters) make a record of satisfactory inspections by dating and initialing the batch record in a space adjacent to where the inspection is indicated to establish inspection status. In-process product also indicates “IN-PROCESS HOLD” status on batch labels (Forms: QA-134A, QA-134A3, and QA-134A4).

In addition to in-process process inspections, quality control tests the product according to in-process specification to establish conformity against the established criteria; status of in-process testing is recorded in QA-185B. In-process product failing to conform to specification is removed and segregated by using a QC HOLD label or MRB Quarantine label. Failed product is not further processed.

Nonconforming products are handled according to SOP Control of Nonconforming Products QP-831.



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5.4.4 **Finished Product**

Finished product is tested according to finished product specification to verify its acceptance as released product.

- 5.4.5 Only the Quality Department is authorized and responsible for releasing finished products for shipment. Sign off on the appropriate Finished Product Specification form and batch record indicates that a product has passed the final inspection. Issuance of Inventory control form (as defined in SOP QA-350) provides the evidence that the product is released. (see QP-825).



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6. APPROVALS

| | |
|-------------------|------|
| Originator | Date |
| Department Head | Date |
| Quality Assurance | Date |

7. CHANGE HISTORY

| Revision# | Date | Reason for change |
|-----------|----------|---|
| 000 | 11/11/96 | Original |
| 001 | 12/1/02 | Combined QP-080 Product Identification and Traceability and QP-120 Inspection Status for ISO 9001-2000 revision. |
| 002 | 10/10/04 | Revised under scheduled SOP revision period. Section 5.5.1, Changed QC inspector to QC personal and added testing with inspection |
| 003 | 08/15/08 | Removed hyperlinks. Removed reference to obsolete procedures and forms (QA-045, QA-050, QA-050D, and QA-134A2). Added reference in Section 4 to procedure QA-030 and Raw Material (RM) & Critical Part (CP) Specification List. Added reference in section 3.3 and 5.1.2 to QC issuing batch numbers for cGMP packaged product. |
| 004 | 2/18/18 | Added reference to ISO 9001-2015 |

Signature Manifest

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Review

| Name/Signature | Title | Date | Meaning/Reason |
|------------------------------------|-------|--------------------------|----------------|
| System Administrator (SYSADMIN) | | 16 May 2023, 12:17:59 PM | Reviewed |